NIH TECHNOLOGY TRANSFER AND YOU

The primary mission of the NIH is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. In pursuing this mission, NIH scientists often discover new technologies. The process of sharing these new technologies with other organizations and the public is called technology transfer. Although not all inclusive, the sharing of new research materials with colleagues, the pursuit of collaborative relationships with outside entities, and the awarding of intellectual property rights to commercial entities for development and commercialization, are all considered technology transfer activities.

Federal technology transfer is governed by a comprehensive set of laws, regulations, and policies. To ensure awareness and compliance with those requirements, every Institute/Center (IC) has designated a Technology Development Coordinator (TDC) who assists IC scientists with technology transfer issues. Your TDC is available to discuss any discovery, proposed collaborative working relationship or sharing of materials.

The following are highlights of some key activities and issues involved in technology transfer.

<u>Material Transfer Agreements (MTAs)</u> NIH uses this mechanism when there is an exchange of materials <u>without</u> an exchange of intellectual property rights. An MTA protects the scientist and the NIH against improper use of materials. It also helps to protect the confidentiality of the material. *Current NIH policy requires that MTAs be used whenever an NIH scientist sends out or receives materials, e.g. cDNAs, cell lines, antibodies, etc. These agreements must be signed by authorized IC personnel.*

The Uniform Biological Material Transfer Agreement (UBMTA) is an MTA that NIH and more than 120 institutions have agreed to use. For institutions which have signed the UBMTA Master Agreement, materials can be transferred upon execution of an Implementing Letter. For further information, contact your IC TDC.

Cooperative Research and Development Agreements (CRADAs) CRADAs are a mechanism used by NIH scientists to collaborate with other organizations outside of NIH. CRADAs allow the exchange of resources including materials, personnel, and equipment among the parties and may confer intellectual property rights. Additionally, funds can be transferred to, but not from, the NIH laboratory/branch to assist in carrying out the project. Since CRADAs involve important legal and ethical constraints on the scientist and the research project, there is a formal clearance process for all NIH CRADAs. A scientist contemplating the use of a CRADA should contact their IC TDC.

<u>Inventions</u> Inventions arise from new discoveries including, but not limited to, vaccines, diagnostics, devices, compounds, research tools, compositions of matter, or any new and useful improvements on existing technologies. *Inventions made by Federal employees and persons under certain other types of appointments belong to the Federal Government and, as required by 45 CFR 7.1, must be reported by using the PHS Employee Invention Report (EIR) Form PHS 6364.*

<u>Patents</u> NIH may seek a patent on a reported invention when it is necessary to facilitate and attract investment by commercial partners for further research and commercial development of the technology.

Dates are critical in patent law because disclosures such as posters, abstracts, talks, public databases or published manuscripts made prior to filing a patent application with the appropriate patent offices may eliminate NIH's ability to obtain comprehensive patent **protection** on an invention. If you believe you have a new invention, it is important to contact your IC TDC who may suggest that you file an Employee Invention Report (EIR) as soon as possible. If an invention exists, there is no reason to wait until preparation of a scientific paper or scheduling of an oral/poster presentation before an EIR is filed.

<u>Licences</u> A license is a mechanism used by NIH to award NIH intellectual property rights to a commercial entity. NIH may seek to license a new technology reported by an employee whether or not that technology is patented. NIH seeks to ensure the development of technologies and the availability of research tools to advance further scientific discovery through the use of various types of licenses.

Royalty Distribution NIH provides financial incentives to inventors from royalty income received under licenses to their inventions. NIH inventors share the first \$2,000 of royalty income received under a license and a percentage thereafter up to a maximum of \$150,000 in royalty income per inventor per year. The remaining income is returned to the IC for use as prescribed by law.

<u>Confidentiality</u> This is an important issue in technology transfer since these activities involve considerable interaction with the private sector. Collaborative agreements, patents, and licenses all require some degree of confidentiality which must be carefully considered and balanced to ensure a thriving scientific enterprise. Confidential Disclosure Agreements (CDAs), signed by ICs and other organizations, are one mechanism which allows signatories to freely exchange information which could be beneficial to the scientific and public health mission of the NIH yet insure that information is not made available to the public prior to official disclosure.

Ethics As stewards of the public trust, Federal employees must always be aware of practicing ethical behavior. This is particularly important for NIH scientists participating in technology transfer activities. NIH scientists must be vigilant in ensuring that they are not using public resources for private and personal gain. NIH scientists should consult their IC TDC and/or Ethics Officer when contemplating technology transfer activities.

To learn more about your rights and responsibilities regarding technology transfer, consult your Institute's Technology Transfer Office:

NIMH Technology Transfer Office Staff:

TTO Director: Kathleen M. Conn

Technology Transfer Specialist: Suzanne L. Winfield, Ph.D.

Technology Development Administrative Specialist: Joyce L. Williams

Phone: 496-8828 FAX: 480-1384

Mailing Address: Building 10, Room 4N222

NIMH Technology Transfer Office Web Site:

http://intramural.nimh.nih.gov/techtran

You may also wish to review the information on the NIH Office of Technology Transfer Web Site: www.nih.gov/od/ott/

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